STENT CONNECTING MEANS

The present invention relates to a stent connecting means and has particular reference to a stent connecting means for use in a bifurcated artery such, for example, as the infrarenal portion of a mammalian aortic artery where it bifurcates to the common iliac arteries.

A stent is used to form a prosthetic intraluminal wall, in the case of a stenosis, to provide an un-obstructed conduit for blood in the area of the stenosis or, in the case of an aneurysm, to remove the pressure on the weakened part of the artery so as to reduce the risk of embolism or of the natural artery wall bursting. Typically, a stent is implanted in the artery of a patient at the site of stenosis or aneurysm by so-called "minimally invasive techniques" in which the stent is compressed radially inwards and is delivered to the site where it is required through the patient's skin in a catheter. When the stent is positioned at the correct location, the catheter is withdrawn and the stent is caused or allowed to re-expand to a pre-determined diameter in the artery.

US-A-4886062 discloses a vascular stent which comprises a length of sinuous or "zig-zag" wire formed into a helix; the helix defines a generally cylindrical wall which, in use, constitutes a prosthetic intraluminal wall. The sinuous configuration of the wire permits radial expansion and compression of the stent; US-A-4886062 discloses that the stent can be delivered percutaneously and expanded in situ using a balloon catheter.

US-A-4733665 discloses an expandable intraluminal graft which is constituted by a tubular member formed from a plurality of intersecting elongate members which permit radial expansion and compression of the stent.

EP-A-0556850 discloses an intraluminal stent which is constituted by a sinuous wire formed into a helix; juxtaposed apices of the wire are secured to one another so that each hoop of the helix is supported by its neighbouring hoops to increase the overall strength of the stent and to minimise the risk of plaque herniation.

The prior art stents mentioned above are satisfactory for the treatment of aneurysms, stenoses and other

angeological diseases at sites in continuous unbifurcated portions of arteries or veins.

However, the prior art stents are not wholly satisfactory for use where the site of desired application of the stent is juxtaposed or extends across a bifurcation in an artery such, for example, as the bifurcation in the mammalian aortic artery into the common iliac arteries. For example, in the case of an aneurysm in the infrarenal portion of the aorta which extends into one of the common iliac arteries, the use of one of the prior art stents referred to above across the bifurcation into the one iliac artery will result in obstruction of the proximal end of the other common iliac artery; by-pass surgery is therefore required to connect the one iliac artery in juxtaposition with the distal end of the stent to the other blocked iliac artery. It will be appreciated by a person skilled in the art that it is desirable to avoid surgery wherever possible; the requirement for by-pass surgery associated with the use of the prior art stents in juxtaposition with a bifurcation in an artery therefore constitutes a significant disadvantage.

According to one aspect of the present invention there is provided a stent connecting means for connecting two intraluminal stents one to the other to define a continuous lumen through the two stents, said stent connecting means comprising:-

a first stent including a male engaging portion which can be compressed radially inwardly; and

a second stent including a female cooperating portion;

wherein the male engaging portion can be entered into the female cooperating portion in a radially compressed state and thereafter caused or allowed to expand in the female cooperating portion; the arrangement being such that in service the interengagement of the male engaging portion and the female cooperating portion serves to resist longitudinal separation of the two stents one from the other.

Typically, the first stent may include a proximal male engaging portion; the second stent may include a distal female cooperation portion. The male engaging

portion may be flared radially outwardly towards its extremity, and the female cooperating portion may be tapered radially inwardly towards its extremity. In some embodiments, the male engaging portion may comprise a frustoconical wall which flares outwardly towards its longitudinal extremity; the female engaging portion may comprise a frustoconical wall which tapers radially inwardly towards its longitudinal extremity.

The male engaging portion of the first stent may be resiliently compressible in a radially inwards direction such that in the radially compressed state it is capable of self-reexpansion to engage in the female cooperating portion. Typically, each of said first and second stents may be resiliently compressible. In use therefore the second stent may be delivered in a radially compressed state e.g. by using a catheter as described in EP-A-0556850; when the second stent is located at the site of use, the catheter may be withdrawn thereby allowing the second stent to re-expand to engage the endoluminal surface of the blood vessel. The first stent may then be delivered percutaneously to a site distally of the second stent such that the male engaging portion of

the first stent in the radially compressed state is entered into the expanded female cooperating portion of the second stent; the catheter may then be withdrawn allowing the first stent to re-expand such that the male engaging portion engages in the female cooperating portion of the second stent.

In some embodiments of the present invention the second stent may have two transversely spaced distal female cooperating portions; the second stent may therefore constitute a bifurcated stent for use in juxtaposition with an arterial bifurcation. Each of the two transversely spaced distal female cooperating portions may be adapted for connection to a first male stent which, in use, extends across the arterial bifurcation into a respective one of the branch arteries.

Alternatively, in a particular aspect of the present invention there is provided a bifurcated intraluminal stent for use in juxtaposition with an arterial bifurcation; the bifurcated intraluminal stent comprising a proximal portion adapted to be positioned in service in an artery in juxtaposition with an arterial bifurcation, a first distal stent portion

adapted to extend across the bifurcation in to one of the branched arteries and a second distal stent portion adapted to allow blood to flow from the proximal portion into the other branched artery. The first distal stent portion may be formed integrally with the proximal portion.

In some embodiments the second distal stent portion may comprise a female cooperating portion which is adapted to engage a male engaging portion of a another stent adapted to extend in the other branched artery such that, in use, the bifurcated stent can be connected in situ to the other stent. The bifurcated intraluminal stent may therefore constitute a second stent in accordance with the present invention comprising a distal female cooperating portion disposed intermediate the proximal and distal extremities of the stent; the other stent may constitute a first stent in accordance with the present invention.

Typically, the bifurcated intraluminal stent may be adapted for use in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries. In use therefore the

bifurcated stent may be introduced percutaneously into the infrarenal portion of the aorta e.g. using a catheter as described in EP-0556850 such that the first distal stent portion extends into one of the branched iliac arteries; the catheter may then be withdrawn allowing the stent to re-expand in situ. If required the other stent may be introduced percutaneously in a radially compressed state such that the male engaging portion of the other stent is engaged in the intermediate female cooperating portion of the bifurcated stent; the other stent is then caused to allowed to re-expand in situ such that the male engaging portion engages in the female cooperating portion to resist longitudinal separation of the two stents in service.

Typically, the proximal end of the second stent may be flared radially outwardly towards its extremity to engage the endoluminal surface of the artery thereby to resist longitudinal movement of the second stent in service.

Each of the first and second stents may comprise a sinuous wire formed into a tubular configuration. The sinuous and tubular configurations may be imparted to

the wire by winding on a mandrel. Typically, each stent may be made from a high memory nitinol wire which may be wound on to the mandrel to form the stent in a tubular configuration of slightly greater diameter than the diameter of the artery in which the stent is intended to be used. The stent may be annealed at an elevated temperature and then quenched so that the nitinol wire "remembers" the configuration in which it was wound on the mandrel. Typically, the annealing may be conducted at about 500°C for about 60 minutes; the quenching may be effected by immersing the wire while still wound on the mandrel in cold water. Typically, the cold water may have temperature of less than about 10°C; the wire may be immersed for about 5 minutes or more.

In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may formed into a plurality of hoops such that the plane of each hoop is substantially perpendicular to the longitudinal axis of the stent. Each hoop may comprise a substantially complete turn of the wire having a sinuous configuration; as each hoop is completed,the point of winding the wire may be displaced longitudinally with

respect to the winding axis to form the next hoop. When the next hoop is complete, the point of winding is moved further longitudinally with respect to the winding axis to the form the next succeeding hoop and so on.

It will appreciated that the advantage of this arrangement is that the planes of the hoops are not skewed with respect to the longitudinal axis of the stent, so that when the stent is caused or allowed to expand in situ there is substantially no twisting of the stent as it shortens in length. It will be appreciated that this represents a significant advantage as in areas of stenosis or aneurysm it is desirable to minimise the movement of the stent within an artery so as to reduce the potential trauma to the patient.

Typically, the stent may comprise a dsecuring means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighbouring hoop so that each hoop is supported by its neighbours. The securing means may comprise a loop element to tie the juxtaposed apices together; the loop element may comprise a loop formed of a thermoplastics material such, for example, as polypropylene.

The male engaging portion and female cooperating portion of the first and second stents respectively may be formed separately from the remainder of their respective stents and then secured thereto by securing means.

The proximal and distal stent portions of the bifurcated stent in accordance with the present invention may be formed separately; the distal end of the proximal stent portion may be secured to the wider proximal end of a first intermediate frustoconical stent portion; the narrower distal end of the first intermediate frustoconical stent portion may be secured to the proximal end of the distal stent portion. The female cooperating portion of the bifurcated stent may be constituted by a second frustoconical stent portion which is secured to the distal end of the proximal stent portion in juxtaposition with the first frustoconical portion.

Each of the first and second stents of the present invention may include a tubular graft layer formed from a biocompatible fabric in juxtaposition with the wire skeleton; typically the graft layer may be disposed internally of the wire skeleton. In some

embodiments the graft layer may be secured to the wire skeleton by loop elements such, for example, as loops of polypropylene.

The biocompatible fabric may be a polyester fabric or a polytetrafluoroethylene fabric.

In some embodiments the male engaging portion of the first stent and the female cooperating portion of the second stent may be left uncovered.

The second stent may be provided on its external surface with circumferentially spaced wire barbs or hooks adapted to engage in the endoluminal surface of the host artery to resist longitudinal movement or slippage of the stent in use. Typically the barbs or hooks may be disposed on part of the stent which is provided with a fabric graft layer such that in use the points of the artery which are engaged by the barbs or hooks are covered by the fabric graft. It will be appreciated by a person skilled in the art that the trauma to the artery wall caused by the hooks or barbs may cause emboli; the provision of the fabric graft over the barbs or hooks in use will therefore help to prevent the introduction of such emboli into the blood stream.

The male engaging portion for the first stent may be provided with circumferentially spaced hooks or barbs on its external surface to engage the internal surface of said female cooperating means, thereby to reinforce the connecting means against longitudinal separation of the stents in the service.

The present invention therefore provides a connecting means for connecting two stents longitudinally one to the other. It will be appreciated that this represents a significant step forward in the art as it allows the provision of a bifurcated stent for use in juxtaposition e.g. with arterial bifurcations without requiring by-pass surgery to connect one of the branched arteries to the other branched artery. In particular, the invention provides a bifurcated stent which can be positioned in an artery in juxtaposition with a bifurcation to extend into one of the branched arteries; the bifurcated stent can be connected to another stent which extends into the other branched artery. The stents can be delivered percutaneously and connected together in situ thereby to provide effective treatment of an angeological disease such, for example, as an aneurysm or a stenosis which extends across a bifurcation in a blood vessel without the need for by-pass surgery.

Following is a description by way of example only and with reference to the accompanying drawings of methods of carrying the present invention into effect.

In the drawings:-

Figure 1a is a side view of a bifurcated intraluminal stent in accordance with the present invention.

Figure 1b is a side view of another stent which is adapted to be be connected to the bifurcated stent of Figure 1a;

Figure 2 is a side view of part of the bifurcated stent of Figure 1a opened up to show its construction;

Fgigure 3 is a side view of another part of the bifurcated stent of Figure 1a opened up to show its construction;

Figure 4 is a side view of yet another part of the bifurcated stent of Figure 1a opened up to show its construction;

Figure 5 is a schematic perspective view of a different bifurcated stent in accordance with the present invention;

Figure 6 is a schematic view of yet another bifurcated stent in accordance with the present invention.

A bifurcated stent in accordance with the present invention which is indicated at (10) in Figure 1a comprises a wire skeleton which is constructed in four separate parts, namely a proximal part (12) a first frustoconical part (14) a second distal part (16) and a second frustoconical part (18). The stent shown in Figure 1a is adapted for use in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries; it will be appreciated, however, that bifurcated stents for use in different parts of the angeological system and for different mammals can be constructed in accordance with the invention by varying the dimensions of the stent accordingly.

Each of the four parts of the bifurcated stent (10) is made in substantially the same way by winding a high memory nitinol wire, typically nitinol type m wire, onto a mandrel.

The construction of the proximal part (12) of the bifurcated stent (10) is shown in Figure 2;

nitinol wire type m wire having a diameter of 0.46mm (0.018") is wound around the mandrel to form a plurality of hoops (20). The winding surface of the mandrel is provided with a plurality of upstanding pins disposed in a zig-zag pattern for each of the hoops (20) so that in each hoop (20) the nitinol wire follows a sinuous path to define a plurality of circumferentially spaced apices (22). Each hoop is wound onto the mandrel such that the plane of the hoop is substantially perpendicular to the longitudinal axis of the mandrel. When one hoop (20) e.g. the hoop indicated at (20^a) has been formed the point of winding of the nitinol is displaced longitudinally with respect to the mandrel axis to form the next successive hoop (20^b) as shown at (21) in Figure 2. The proximal part of the bifurcated stent is formed on the mandrel with a diameter of about 24mm and a length in the longitudinal direction of about 55mm. From Figures 1a and 2 it will be noted that the proximal part (12) is constituted by three hoops (20) of unit width at the proximal end (24) of the proximal part (12), two intermediate hoops (25) of twice unit width and, at its distal end (26), by a single hoop (20) of unit width.

When the nitinol wire has been wound onto the mandrel, the nitinol wire is annealed at an elevated

temperature and then quenched. In this embodiment of the invention the wire is annealed at a temperature of about 500°C for 60 minutes and is quenched by immersing the mandrel in wire in cold water at less than 10°C for about 5 minutes. The purpose of the annealing and subsequent quenching is so that the nitinol wire "remembers" its configuration as wound on the mandrel; it will be appreciated therefore that other temperatures and durations for the annealing and quenching steps are included within the present invention provided the nitinol wire "remembers" its wound configuration.

After annealing and quenching, the wire is removed from the mandrel, and juxtaposed apices (22) of neighbouring hoops (20) are secured together using, in this example, 0.003" polypropylene filaments. In the proximal part shown in Figure 2, each apex (22) of each hoop (20) which has a juxtaposed apex of a neighbouring (20) is tied to the juxtaposed apex (22). It will be appreciated, however, that in other embodiments of the invention only some of the juxtaposed apices (22) may be secured in this way.

The first and second frustoconical parts (14, 18) of the skeleton are formed in substantially the same way

as the proximal part (12) by winding nitinol wire onto a mandrel and then annealing and quenching the wire before removing it from the mandrel. As shown in Figure 3, the first and second frustoconical parts (14,18) are each constituted by three hoops (20) of unit width. The mandrel is tapered such that the proximal end of each of the frustoconical parts (14,18) is formed with a diameter of about 12mm and the distal end (32) of each is formed with a diameter of about 9mm. The overall length of each of the frustoconical parts (14,18) is about 18mm. The wire used for the frustconical parts (14,18) is nitinol type M wire having a diameter of 0.28mm (0.011"). Juxtaposed apices (22) of each of the frustoconical parts (14,18) are tied together using 0.03" polypropylene filaments as described above. The first and second frustoconical parts (14,18) are secured to the distal end (26) of the proximal part (12) of the stent (10) in transverse by spaced relation as shown in Figure 1a by securing the apices (22) of the hoop (20) forming the wider proximal end (30) of each of the frustoconical parts (14,18) to juxtaposed apices (22) of the hoop (20) on the distal end (26) of the proximal part (12).

The distal part (16) of the bifurcated stent (10) is formed by winding nitinol type M wire having a diameter of 0.28mm (0.011") onto a mandrel to form twelve longitudinally spaced hoops (20) as shown in Figure 4; the distal part has an overall length of about 66mm and a uniform diameter of about 9mm. The proximal end (34) of the distal part (16) is secured to the narrower distal end (32) of the first frustoconical part (14) by tying each apex (22) on the proximal end (34) of the distal part (16) to a juxtaposed apex on the distal end (32) of the first frustoconical part (14) using 0.003" polypropylene filaments.

The proximal part (12) and distal part (16) are each covered with a tubular graft layer of a biocompatible woven fabric (not shown) such, for example, as woven 30 denier polyester; the first and second frustoconical parts (14,18) are not covered. The tubular fabric layers are attached to the proximal and distal parts (12,16) of the stent (10) by stitching with 0.003" polypropylene filaments around the apices (22) of the underlying skeleton.

The proximal part (12) of the skeleton is provided with a plurality of circumferentially spaced hooks or barbs (not shown) which project through the tubular

fabric layer to engage in the endoluminal surface of a host artery in service.

The sinuous configuration of each turn (20) of the wire skeleton of the stent (10) allows the stent (10) to be compressed resiliently radially inwards so that it can be received in a catheter e.g. a 12 or 14 French catheter for percutaneous delivery to an intraluminal site in the infrarenal section of the aortic artery. Nitinol wire is an x-ray opaque material; the percutaneous administration can therefore be monitored using x-rays. The bifurcated stent (10) is positioned in the infrarenal section of the aortic artery in juxtaposition with the bifurcation of the common iliac arteries such that the distal part (16) of the stent extends into one of the common iliac arteries. The catheter is then withdrawn allowing the stent (10) to re-expand towards its configuration as wound on the mandrel in which is was annealed and quenched until the stent engages the endoluminal surface of the host artery. The barbs or hooks engage the endoluminal surface of the host artery to resist longitudinal displacement or slipping of the stent (10) in use.

It will be appreciated that when the bifurcated stent is positioned and re-expanded in the fitted position, blood can flow from the aortic artery into the proximal part (12) of the stent from where it can flow into the one common iliac artery through the frustoconical part (14) and the distal part (16) and also into the other common iliac artery through the second frustoconical part (18).

In cases where it is required to implant a stent in the other common iliac artery a second stent (40) as shown in Figure 1b can be used. The second stent (40) incudes a wire skeleton comprising a proximal frustoconical part (42) and a distal part (44).

The frustoconical proximal part (42) is constructed in the same way as the frustoconical parts (14,18) of the bifurcated stent (10); the distal part (44) is constructed in the same way as the distal part (16) of the bifurcated stent (10). The distal end of the frustoconical proximal part (42) is secured to the proximal end of the distal part (44) by securing juxtaposed apices using polypropylene filaments as described above.

In use, the second stent (40) is compressed radially inwards and is received in a catheter for percutaneous delivery to the other common iliac artery. The frustoconical proximal part (42) is guided, in the radially compressed state, into the second frustoconical part (18) of the bifurcated stent (10). The catheter is then withdrawn allowing the second stent (40) to re-expand towards its remembered configuration, until the distal part (14) engages the endoluminal surface of the other common iliac artery, and the outer surface of the frustoconical proximal part (42) engages the interior surface of the second frustoconical part (18) of the bifurcated stent (10).

The frustoconical proximal part (42) is formed with circumferentially spaced barbs or hooks (not shown) which engage in the wire skeleton of the second frustoconical part (18) of the bifurcated stent (10). The tapered configurations of the second frustoconical part (18) of the bifurcated stent (10) and of the proximal frustoconical part (42) of the second stent (40) are such that in the fitted position as described, the stents are locked together to resist longitudinal separation in service, the barbs or hooks on the second stent (40) help to resist such longitudinal separation.

The distal part (44) of the second stent (40) is covered with a tubular graft layer of a biocompatible fabric such, for example, as polyester or polyfluoroethylene fabric (not shown).

In a variant of the present invention a bifurcated stent (50) as shown in Figure 5 includes a wire skeleton comprising a frustoconical proximal portion (52) which tapers radially inwardly from its proximal end (54) to its distal end (56), and first and second transversely spaced frustoconical distal portions (58,60) which are secured to the distal end (56) of the frustoconical proximal portion (52); the frustoconical proximal portion (52) is covered with a tubular graft layer of a biocompatible fabric (62).

In use the stent (50) is delivered percutaneously to an artery in juxtaposition with an arterial bifurcation; blood can flow through the frustoconical proximal portion (52) into each of the branched arteries through the first and second distal frustoconical portions (58,60). If a stent is required in one or both of the branched arteries, a separate stent of the type shown in Figure 1b referred to above can be connected to the stent (50) by

inserting and re-expanding the proximal end of such a separate stent in one or both of the distal frustoconical portions (58,60) of the stent (50) for engagement therein.

Another variant of the present invention is shown in Figure 6 which shows a bifurcated stent (70) which is similar to the bifurcated stent (50) shown in Figure 5 except the proximal part of the stent (70) is generally cylindrical rather than frustoconical; the method of attachment of stents of the type shown in Figure 1b to the bifurcated stent (70) is shown schematically in Figure 6.

CLAIMS

1. A stent connecting means for connecting two intraluminal stents one to the other to define a continuous lumen through the two stents, said stent connecting means comprising:-

a first stent including a male engaging portion which can be compressed radially inwardly; and

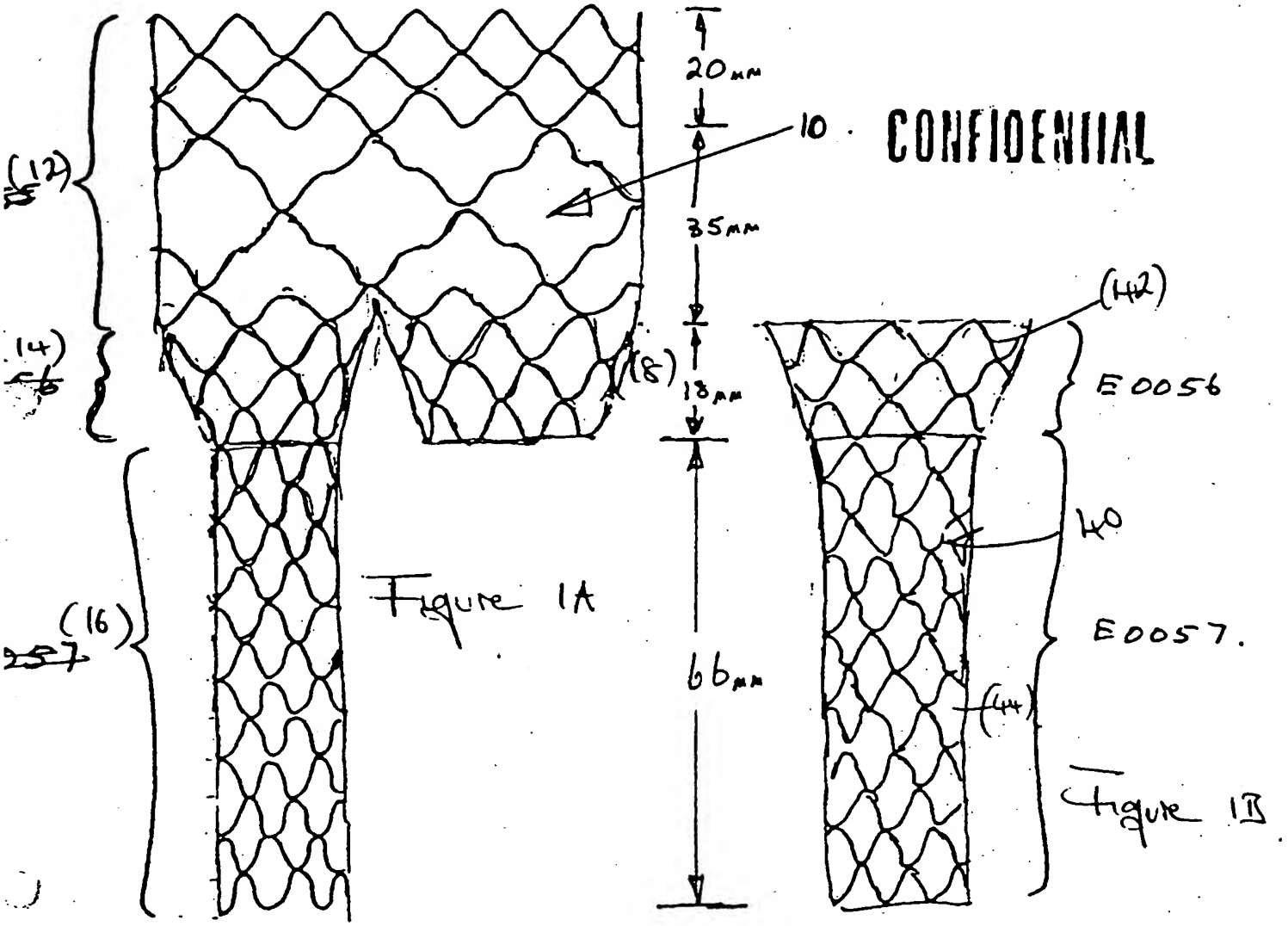
a second stent including a female cooperating portion;

wherein the male engaging portion can be entered into the female cooperating portion in a radially compressed state and thereafter caused or allowed to expand in the female cooperating portion; the arrangement being such that in service the interengagement of the male engaging portion and the female cooperating portion serves to resist longitudinal separation of the two stents one from the other.

2. A bifurcated intraluminal stent for use in juxtaposition with arterial bifurcation; the bifurcated intraluminal stent comprising a proximal portion adapted to be positioned in service in an artery in juxtaposition with an arterial bifurcation, a first distal stent portion adapted to extend across the bifurcation in to one of the branched arteries and a second distal stent portion adapted to allow blood to flow from the proximal portion into the other branched artery.

AAA Bifurcated Stent. - Schematic Construction

Version 1-3-94



OVERALL LENGTH 139mm.

DRAWING # E 0062

1-3-94

AAA Bifurcated Stent Construction.

Version 1-3-94

JOH 1-3-94

AORTA SECTION 24 mm DIAMETER

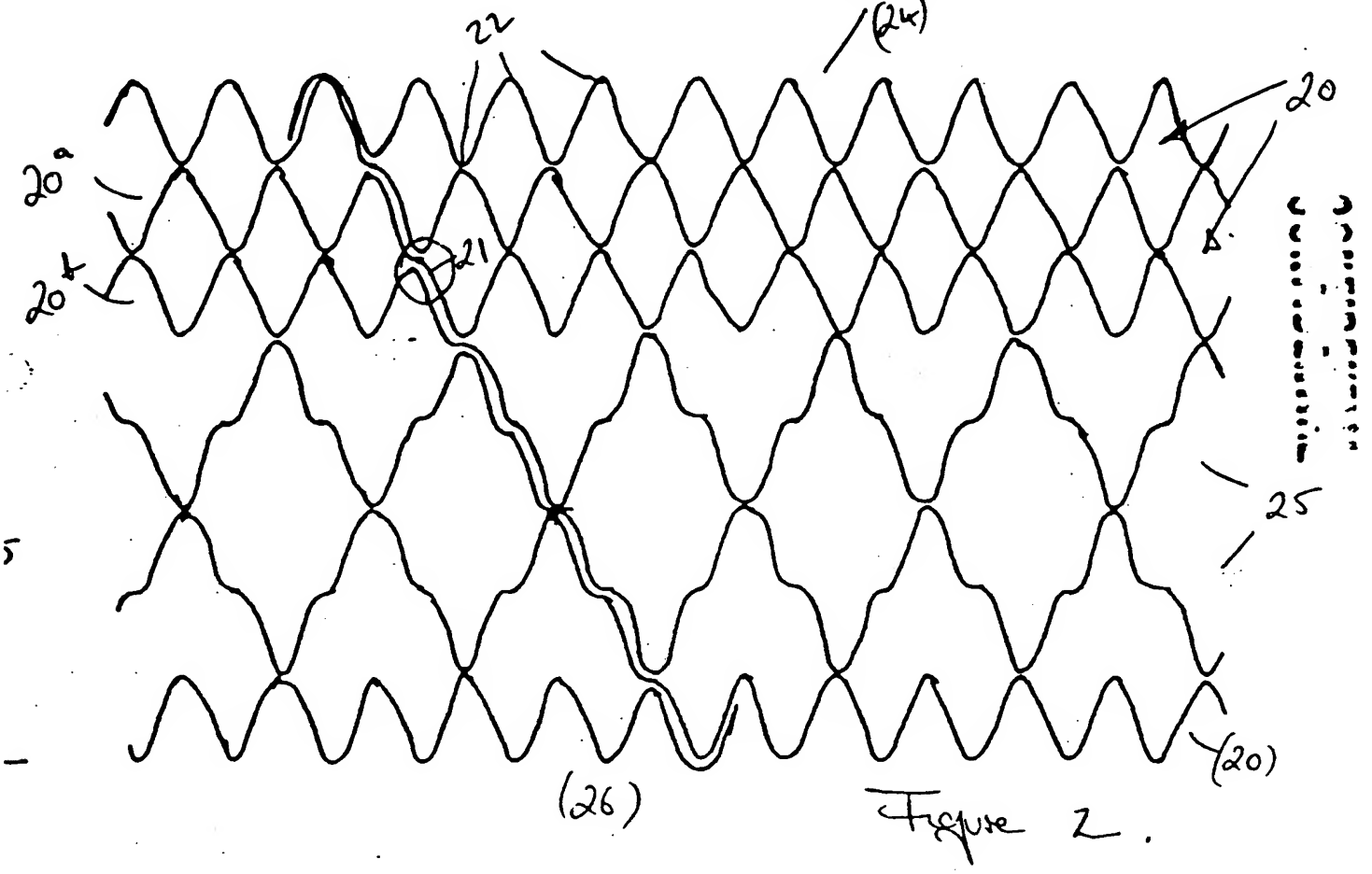


Figure 2.

Wire Nitinol Type M diameter 0.018" (0.46 mm)

Wound on Mandrel Drawing # E0037

Anneal at 500°C for 60 minutes.

Cool in air. - Remove from mandrel in water < 10°C
Totally immerse in cold water for 5 minutes
before wire removal.

Tie using 0.003" polypropylene. 3 wraps per knot.

DRAWING # E0055 REV 1

1-3-94

AAA Bifurcated Stent Construction Version 1-3-94

CONFIDENTIAL

ILLIAC TAPER SECTION 12/9 mm DIAMETER (FOR 24 mm AORTA)

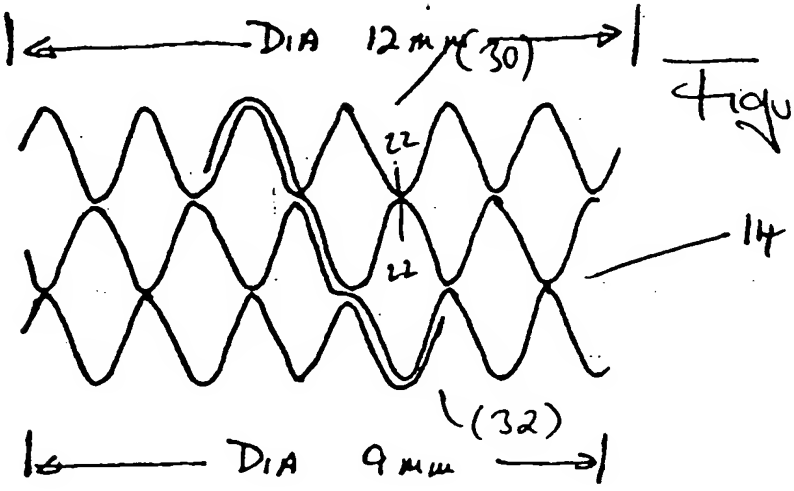


Figure 3 -

TAPERED CONSTUCTION

NOT TO SCALE

Wire Nitinol Type M diameter 0.011" (0.28mm)
Wound on mandrel Drawing # E0053
Anneal at 500°c for 1 hour.
Tie .003" polypropylene 2 wraps per knot.

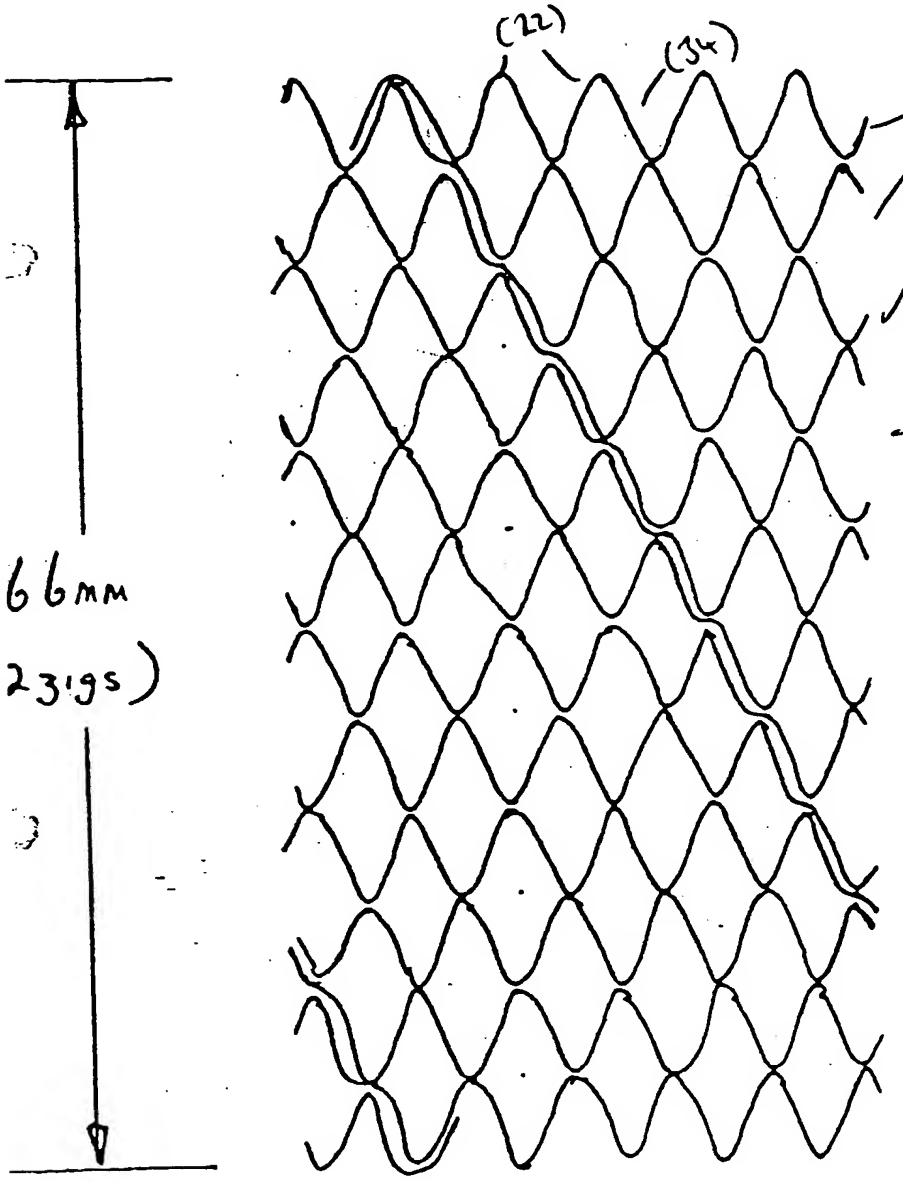
DRAWING # E0056

SM
1-3-94

AAA Bifurcated Stent Construction Version 1-3-94

ILIAC SECTION 9mm dia (For 24 mm AORTA)

wire Nitinol type M dia 0.011" (0.28 mm)
anneal at 500°C for 60 minutes on MANDREL E0052



CONFIDENTIAL

Figure 4

DRAWING # E0057 REV. 1

1-3-94

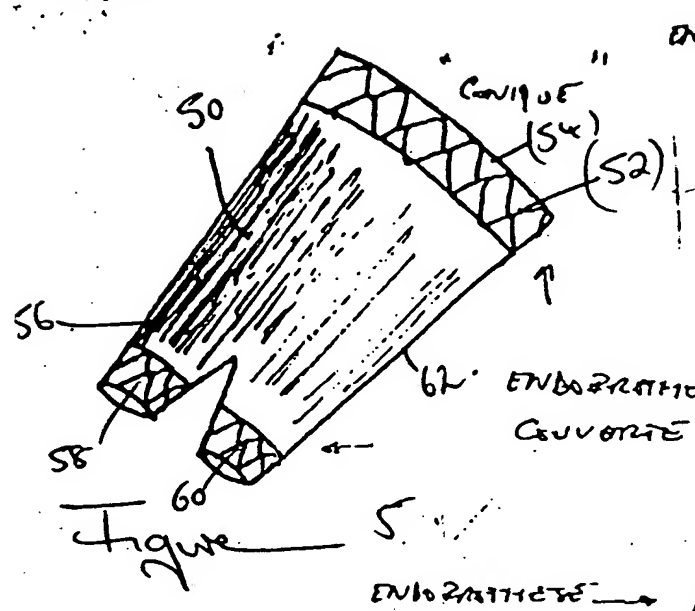


Figure 5

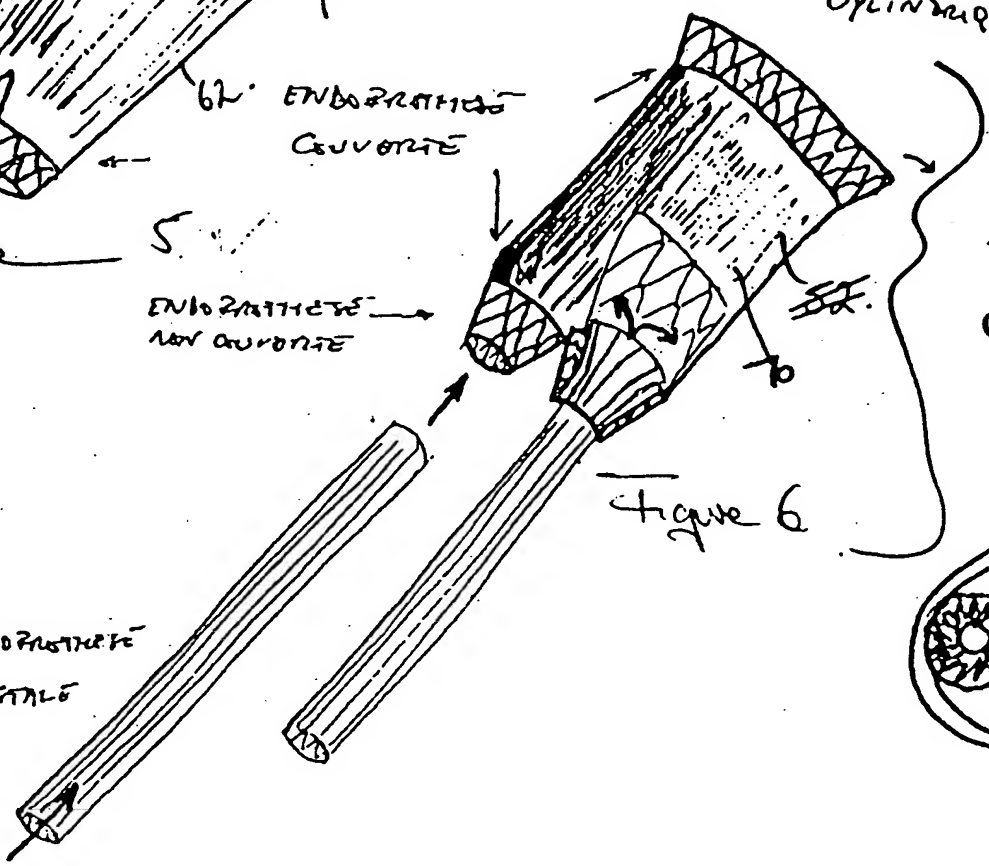
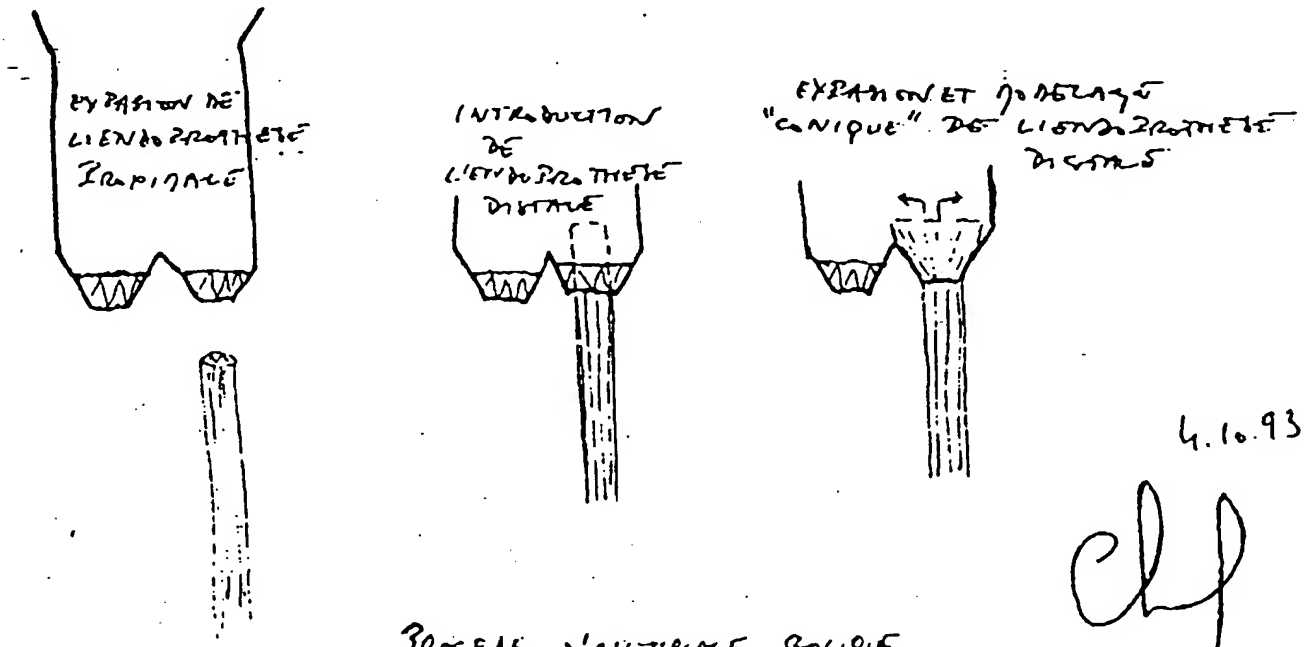


Figure 6



4.10.93

PROCESSE D'ASSEMBLAGE CONIQUE POUR ENDOPROTHÈSES